DEPARTMENT OF MENTAL HEALTH
POLICY/PROCEDURE

SUBJECT	POLICY NO.	EFFECTIVE DATE	PAGE
MENTAL HEALTH RESEARCH REVIEW	**1400.01**	**09/16/2013**	**1 of 9**
APPROVED BY:  Director	SUPERSEDES **109.01 09/16/2013**	ORIGINAL ISSUE DATE **01/10/1980**	DISTRIBUTION LEVEL(S) **1, 2**

PURPOSE

1.1 To establish a mechanism for review and approval of human subjects research activities involving staff, clients or data related to Los Angeles County Department of Mental Health (LACDMH or Department) directly-operated programs and legal entity contracted providers.

DEFINITION

2.1 **Research, per 45 CFR 46.102(d)**: "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities". (Authority 1)

2.2 **Human Subject, per 45 CFR 46.102(f)*:*** " …a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (Authority 2)

2.3 **Human Subjects Research Committee (HSRC), per LACDMH Policy No. 500.05, Use and Disclosure of Protected Health Information for Research**: "An LACDMH committee which is responsible for the review of all research protocols which include LACDMH clients as research subjects [within LACDMH programs] including those research protocols already approved by an Institutional Review Board (IRB) to assure that all research is conducted in accordance with the standards and policies of LACDMH. The HSRC is not an IRB. The HSRC provides an extra level of human subjects protection with respect to LACDMH clients." (Reference 1)

2.3.1 Contractors of LACDMH are not subject to LACDMH Policy No. 500.05 but are subject to their relevant internal policies and all relevant provisions of federal and State legal requirements pertaining to Health Insurance Portability and Accountability Act (HIPAA) Privacy, safeguarding of client information, and other applicable statutes and regulations that govern human research.

2.4 **Principal Investigator (PI)**: An individual with primary responsibility for research grant or project.

POLICY

3.1 All approved research shall:

3.1.1 have the intent of increasing the body of knowledge pertaining to the mental health field;

3.1.2 be consistent with the Department's mission;

3.1.3 be consistent with applicable Department conflict of interest policies;

3.1.4 use Department resources appropriately;

3.1.5 be consistent with applicable ethical values; and

3.1.6 be consistent with applicable laws, regulations, and policies.

3.2 All proposed human subjects research activities that involve directly-operated and/or contracted programs operated by legal entity providers must first be reviewed by the LACDMH HSRC before commencing research activities. The HSRC is responsible for:

3.2.1 Reviewing all research protocols involving clients as defined in Section 1.1 of this policy, including those already approved by an IRB to assess whether the investigator has the capacity to conduct research in accordance with LACDMH Policies, Procedures, and Parameters. The

HSRC will also review protocols which involve the use of LACDMH data or other resources, such as staff time or clinic space.

3.2.2 Ensuring that human subjects' protection is present in all research activities involving LACDMH programs.

3.3 HSRC will recommend the suspension or termination of an approved research project that is not being conducted in accordance with the HSRC's requirements or that has been associated with unexpected serious harm to participants.

3.4 The executive manager overseeing the facilities, resources or programs involved in the proposed research is responsible for administrative approval to commit resources and to identify relevant issues (i.e., regarding the use of LACDMH resources at the clinic level, suitability of the particular program for participation, applicable site-specific conditions, etc.) for consideration by the HSRC.

3.4.1 LACDMH staff of directly-operated programs who participate in research activities must have approval of a supervisor (Program Manager or above), who reviews any potential research activity in order to avoid confusion of roles and identify conflicts of interest.

3.4.2 Investigators who are not LACDMH staff and who will conduct research on site at a LACDMH directly-operated facility such as a clinic must register as LACDMH volunteers.

3.4.3 All LACDMH services provided as part of research activities must fully meet Departmental clinical, programmatic, and fiscal requirements, including those related to practice parameters, policies and procedures, and medical necessity.

3.5 Research activities shall not result in any denial or delay in a client receiving appropriate services. Clients shall always be made aware of activities that are research-related or research-sponsored as opposed to usual services.

3.6 Only those studies approved by LACDMH HSRC may post recruitment flyers for research volunteers in LACDMH contracted or directly operated facilities.

3.7 The HSRC may set priorities (e.g., relevance to program needs, etc.) that affect timeframes for proposal review and possible approval in order to ensure compliance with the LACDMH mission and adequate protection of LACDMH clients.

PROCEDURE

4.1 Membership of the HSRC

4.1.1 The membership shall consist of representatives of the different LACDMH bureaus, including, but not limited to, Patients' Rights, Compliance, Medical Director's Office, Quality Improvement, Empowerment and Advocacy, and other representatives as determined by the LACDMH Director.

4.1.2 HSRC members shall possess various qualifications and experiences.

4.1.3 HSRC shall consist of at least five (5) members.

4.2 HSRC Meetings

4.2.1 HSRC meetings shall be scheduled as necessary, depending on the number of pending applications for review.

4.2.2 HSRC meeting minutes will include a record of attendance, proposals discussed, and any recommendations by the HSRC.

4.2.3 HSRC may elect to invite investigators to appear before the HSRC in person or by teleconference.

4.3 HSRC Notifications

4.3.1 HSRC Chair shall notify investigators in writing of decisions made or modifications required.

4.3.2 If HSRC review results in failure to approve a research activity, the HSRC Chair shall provide a written notification including a statement of the reason for its decision. Investigators may reapply in the event of the HSRC non-approval.

4.3.3 HSRC will notify the appropriate PI in the event that an HSRC approved research project is being suspended or terminated for any reason including failure to conduct research in accordance with the HSRC's requirements or unexpected serious harm to participants.

4.4 HSRC Records

4.4.1 HSRC shall maintain adequate documentation of its activities including copies of all research applications, annual reports, and HSRC meeting minutes, and a list of HSRC members.

4.4.2 Records listed above shall be retained for at least six (6) years or at least three (3) years after completion of research, whichever is longer.

4.4.3 Per LACDMH Policy No. 500.05, documentation related to waivers approved by the HSRC will be retained for six (6) years after the research is complete.

4.5 Criteria for Approval of Research

4.5.1 The research is of sufficient importance to the mission of the Department to justify department participation.

4.5.2 The risk to participants is minimized to the greatest extent possible and is reasonable in relation to anticipated benefits, if any, including the importance of the knowledge that can reasonably be expected to result from the research.

4.5.3 The selection of participants is equitable.

4.5.4 Informed consent of human subjects, unless waived, is sought and appropriately documented. Requests for waiver or alteration of consent process shall require documentation regarding the level of risk, effect on the rights or welfare of participants, and practicality of conducting research without a waiver. Requirement for a waiver of consent documentation shall include documentation regarding risk, whether the consent would be the only link with participants, and risk of breach in confidentiality.

4.5.5 There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

4.5.6 Adequate safeguards are included to protect the rights and welfare of vulnerable populations.

4.5.7 The research design appears sufficiently scientifically sound to reasonably expect results that are valuable to the mission of LACDMH.

4.5.8 Investigators are qualified and have appropriate experience to carry out the proposed research.

4.5.9 Investigators and responsible LACDMH workforce must adhere to applicable conflict of interest policies;

4.5.10 Research projects have IRB approval from their home institution's federally registered IRB. These IRBs must include an association with a specific research institution located in Los Angeles County. Other IRBs may be considered on a case-by-case basis.

4.5.11 Case studies must be reviewed by the HSRC for purposes of determining the sufficiency of the de-identification of Protected Health Information (PHI) in instances where they meet the definition of research (Section 2.1 of this policy for research definition).

4.5.12 An HSRC Application for Research Approval must be fully and accurately completed and must include any required supplemental

documents and appendices. The completed application must be signed by the PI and submitted to the HSRC.

4.6 Types of HSRC Outcomes

4.6.1 **Approval**: The Department approves the research project.

4.6.2 **Conditional Approval**: Minor changes are requested. Full approval commences when documentation of requested changes is received.

4.6.3 **Time Limited Approval**: Approval is for less than one (1) year, after which all approvals must be renewed.

4.6.4 **Non-Approval**: Application and/or supplemental documents and appendices did not meet criteria for approval for research. Resubmissions will be considered.

4.7 Exemptions from Review Procedures

4.7.1 Research projects are exempt from full HSRC review if the research falls into one (1) or more of the six (6) federally defined categories specified in 45 CFR, 46.101(b) (Authority 3).

4.7.2 The chairperson or an HSRC member designated by the chairperson must determine that a project is eligible for exemption.

4.7.3 The research protocol must have received exempt approval from its home institution's designated IRB.

4.8 Continuing Review

4.8.1 Investigators are required to submit documentation to keep the HSRC updated as to the progress of the research, recruitment of participants, and occurrence of significant adverse events, e.g., death or injury requiring medical treatment. Typically, continuing review reports are to

be provided on an annual basis; however, in some instances, the HSRC may require more frequent reporting.

4.9 Final Report

4.9.1 Investigators are required to submit a final report to HSRC within 90 calendar days after the completion of the research project.

4.9.2 Failure to provide a final report may result in sanctions up to and including prohibition against any future research being conducted within the Department and formal complaints to relevant agencies.

4.10 Publications

4.10.1 All investigators must submit abstracts and/or manuscripts to HSRC prior to publication in addition to copies of publications resulting from the research as they become available.

4.10.2 HSRC will review and provide editorial suggestions.

4.10.3 Failure to provide abstracts and/or manuscripts may result in sanctions up to and including prohibition against any future research being conducted within the Department and formal complaints to relevant agencies.

AUTHORITY

1. 45 CFR 46.102(d)
2. 45 CFR 46.102(f)
3. 45 CFR 46.101(b)

ATTACHMENT (HYPERLINKED)

1. HSRC Application for Research Approval

SUBJECT	POLICY NO.	EFFECTIVE DATE	PAGE
MENTAL HEALTH RESEARCH REVIEW	**1400.01**	**09/16/2013**	**9 of 9**

REFERENCE

1. LACDMH Policy No. 500.05, Use and Disclosure of Protected Health Information for Research

RESPONSIBLE PARTY

LACDMH Office of the Medical Director